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|--|-------------|----------------------|---------------------|------------------|
| 10/557,747   | 11/21/2005  | Toru Nishibayashi    | Q91609              | 2298             |
| 23373 7590 06/07/2010<br>SUGHRUE MION, PLLC<br>2100 PENNSYLVANIA AVENUE, N.W.<br>SUITE 800<br>WASHINGTON, DC 20037 |             |                      |                     |                  |
| EXAMINER<br>SZNAIDMAN, MARCOS L  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1612   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/557,747

**Applicant(s)**

NISHIBAYASHI ET AL.

**Examiner**

MARCOS SZNAIDMAN

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on February 16, 2010.

Receipt of Declarations under 37 CFR 1.132 is acknowledged.

#### ***Status of Claims***

Amendment of claim 1 and cancellation of claim 24 is acknowledged.

Claims 1 and 26-27 are currently pending and are the subject of this office action.

Claims 1 and 26-27 are presently under examination.

#### ***Priority***

The present application is a 371 of PCT/JP04/07436 filed on 05/252004.

#### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Petition for Reconsideration***

In response to the Petition filed on June 30 2009 under 37 C.F.R. 1.144 to request reconsideration of the restriction requirement mailed on March 7, 2008, a decision was made to dismiss it. See petition decision mailed on 05/25/2010.

***Claim Rejections - 35 USC § 103 (Maintained rejection)***

Claims 1 and 26-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et. al. (US 5,376,686, cited by applicant, cited in prior office action).

The reasons for this rejection have been provided in the previous office action dated September 15, 2009, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that:

First, Applicants note that the present claims do not merely recite a composition comprising olanexidine and an excipient.

Further, although "polyoxyethylene phenyl ether" is described as a surfactant in Prescriptions 1 and 2 of Ishikawa, Ishikawa nowhere describes nor suggests a "polyoxyethylene- based nonionic surfactant", which is a broader term. More specifically, Ishikawa describes a formulation comprising olanexidine and polyoxyethylene ~ ether, but nowhere discloses a combination of olanexidine with a

polyoxyethylene-based nonionic surfactant. Therefore, the composition of the present invention is clearly different from the formulation of Ishikawa.

Examiner's response:

Ishikawa teaches that polyoxyethylene phenyl ether is a "nonionic surface active agent" (see column 24, first and second lines), or in other words Ishikawa is teaching that polyoxyethylene phenyl ether is a "polyoxyethylene-based nonionic surfactant".

Applicant further argues:

Even further, there is no apparent reason to modify the composition taught by Ishikawa with a reasonable expectation of success in arriving at the claimed invention. That is, there is no teaching or suggestion of the claimed combination and no teaching or suggestion to modify the composition of Ishikawa and to specifically select the polyethylene-based nonionic surfactant of formula (1) as recited in claim 1. It has been established that the prior art must suggest the desirability to modify or combine disclosures. The fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). It is also insufficient to establish *prima facie* obviousness based on the assertion that a modification is within the capabilities of one of ordinary skill in the art without an objective reason to make the modification. See *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993); *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VS1 intl'l Inc.*, 174 F.3d 1308, 50

USPQ2d 1161 (Fed. Cir. 1999); and MPEP § 2143.01. This is consistent with the principals of KSR which acknowledged the importance of identifying a reason that would have prompted a person of ordinary skill in the relevant field to combine elements *in the way the claimed invention does* in an obviousness determination (emphasis added). *KSR v. Teleflex*, 127 S.Ct. 1727, 1731 (2007). For at least this reason, the present invention is not obvious based on Ishikawa.

Examiner's response:

Since Ishikawa teaches a composition comprising olanexidine and a polyoxyethylene-based nonionic surfactant like polyoxyethylene phenyl ether (see columns 23 and 24: prescriptions 1 and 2) and since polyoxyethylene higher alkyl ethers or polyoxyethylene alkylphenyl ethers are known polyoxyethylene-based nonionic surfactants, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (any polyoxyethylene-based nonionic surfactant like polyoxyethylene phenyl ether) for another (polyoxyethylene higher alkyl ethers or polyoxyethylene alkylphenyl ethers) with an expectation of success, since the prior art establishes that both function in similar manner, thus resulting in the practice of claims 1 and 26-27 with a reasonable expectation of success.

Applicant argues:

Moreover, the present invention provides unexpectedly superior results, which are not taught or suggested and could not have been expected from the disclosure of Ishikawa. Applicants submit a Declaration including experimental data on antibacterial activity to demonstrate that based on the above structural difference, the composition of present invention can provide unexpectedly superior results compared to the composition of Ishikawa.

The Declaration clearly demonstrates that "polyoxyethylene alkyl phenyl ether" (Example 2 of the present application) has remarkably higher levels of antibacterial activity than the "polyoxyethylene phenyl ether" of Ishikawa. Further, data on antibacterial activity in the present specification (Tables 2 and 3) show that "polyoxyethylene alkyl phenyl ether" (Example 2) and "polyoxyethylene higher alkyl ether" (Examples 3 to 5) have equally high levels of antibacterial activity. In conclusion, the "polyoxyethylene higher alkyl ether" of the present invention can provide remarkably excellent antibacterial activity compared to the "polyoxyethylene phenyl ether" of Ishikawa.

A feature of the disinfectant of the present invention is that it comprises, in addition to olanexidine, a surfactant containing a terminal alkyl group of a specific chain length (C7-20) (a polyoxyethylene higher alkyl ether). Based on this structural feature, the disinfectant of the present invention exhibits extremely high levels of antibacterial activity.

Comparatively, the "polyoxyethylene phenyl ether" of Ishikawa does not contain an alkyl group having the specific carbon length. Ishikawa nowhere discloses nor

suggests an alkyl group of the specific carbon length. Thus, the effect achieved by the polyoxyethylene higher alkyl ether cannot be predicted from Ishikawa. For this additional reason, the present invention is patentable over Ishikawa.

Examiner's response:

MPEP 716.02(e) states:

"An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." *In re Merchant*, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, *In re Finley*, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. *In re Armstrong*, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential).

Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961) (Claims to a 13-chloro substituted compound were rejected as obvious over



nonchlorinated analogs of the claimed compound. Evidence showing unexpected results for the claimed compound as compared with the 9-, 12-, and 14- chloro derivatives of the compound rebutted the prima facie case of obviousness because the compounds compared against were closer to the claimed invention than the prior art relied upon.)."

The evidence presented by Applicant is not considered appropriate because Applicant is comparing a composition comprising 0.1 g of olanexidine hydrochloride and 0.32 g of POE (10) nonylphenyl ether (FW = 660, 0.484 mmoles) (sample 1 corresponding to applicant's invention) and a composition comprising 0.1 g of olanexidine hydrochloride and 0.075 g of POE (10) phenyl ether (FW = 534, 0.140 mmoles) (sample 2 corresponding to Ishikawa invention). Applicant is comparing two compositions containing the same amount of olanexidine hydrochloride, but with different molar amounts of surfactants: 0.484 mmoles of POE (10) nonylphenyl ether and 0.140 mmoles of POE (10) phenyl ether. So the claimed unexpected properties of the instant application composition might be due simply to the different proportions of surfactants used in each case and not to the surfactant itself. A proper comparison should have been done with the same molar amount of each surfactant.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
June 2, 2010.

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612